REMARKS

The Office Action of December 17, 2009 presents the examination of claims 1-9. Claims 1, 2 and 9 are amended herein to clarify that the methods recited in claim 2-8 are performed using a set of four primers having the nucleotide sequences respectively of SEQ ID NOS: 1-4, and that a composition and article comprising the complete set of four primers is the subject invention of claims 1 and 9, respectively.

Claims 2-8 are indicated as allowed.

Claims 1 and 9 stand rejected under 35 USC § 103(a) as being unpatentable over Salotra '182 in view of Reed WO '331 and Lowe (1990) and Belli (1998). This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Applicants submit that the Examiner has failed to establish *prima facie* obviousness of the claimed invention. At least one feature of the claims is not disclosed or suggested in the combination of the cited references.

The Examiner has fallen victim to hindsight, using the disclosure of the present application to select from the very long gene sequences presented in the cited references those few contiguous basepairs constituting the oligonucleotide primers recited in the instant claims. Such an approach to formulating an obviousness rejection has been repeatedly rebuked by the Court of Appeals for the Federal Circuit. *See, e.g., Sensonics Inc. v. Aerosonic Corp.*, 38 USPQ2d 1551 (Fed. Cir. 1996). Furthermore, claims 1 and 9 recite that a set of four primers of particular sequence are included. This feature is entirely absent from any of the references cited and therefore from their combination.

Furthermore, the specification provides evidence of unobviousness of the claimed invention. As explained in Applicants' previous response, the present invention provides tools to accurately diagnose infection with strains of *Leishmania* that cause either visceral or cutaneous disease. The combined references do not provide such tools. For example, Table 1 of Salotra

relied upon by the Examiner (page 3, para. 6 of the Office Action) shows a positive indication of both of KA (VL) and PKDL strains using the primer set Ld1 (see paragraph [0038] of the reference). In contrast, the primer set of the present invention allows the clinical practitioner to distinguish infection by VL or by PKDL strains.

The above-explained result can be applied either to assert that the cited combination of references fails to establish any expectation of success in making the present invention or as evidence of results unexpected by one of ordinary skill in the art obtained by the invention. Either way, the instant invention as recited in claims 1 and 9 is unobvious over the combination of Salotra '182 in view of Reed WO '331 and Lowe (1990) and Belli (1998), and the instant rejection should be withdrawn.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell, Ph.D., Reg. No. 36,623, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: March 17, 2010

Respectfully submitted,

By _____

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